DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 3, 2014

Stereotaxis, Inc.
% Diane Horwitz, Ph.D., Rac
Safis Solutions LLC
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K140804
Trade/Device Name: Vdrive With V-loop/ Vdrive Duo
Regulation Number: 21 CFR 870.1290
Regulation Name: System, Catheter Control, Steerable
Regulatory Class: Class II (two)
Product Codes: DXX, DQX
Dated: July 29, 2014
Received: July 30, 2014

Dear Diane Horwitz,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

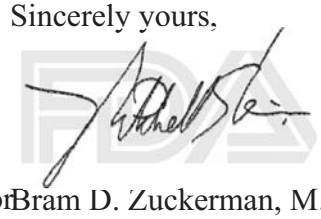
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140804

Device Name
Vdrive™ with V-Loop
Vdrive Duo™

Indications for Use *(Describe)*
The Vdrive™ system is intended to stabilize, navigate and remotely control:
• compatible loop (circular) mapping catheters to facilitate movement of the catheter during the performance of electrophysiological procedures when used in conjunction with the V-Loop™ disposable sets in the Vdrive™ system.
• compatible Intracardiac Echocardiography (ICE) catheters to facilitate visualization of cardiac structure during the performance of cardiac procedure when used in conjunction with the V-Sono™ disposable sets in the Vdrive™ system.

The Vdrive™ with V-Loop™ disposable is indicated to remotely control the advancement, retraction, rotation, tip deflection and loop size of compatible loop catheters inserted across the septum into the left atrium using conventional procedures. Compatible catheters at this time include Biosense Webster Lasso 2515 and Lasso 2515 NAV Circular Mapping Catheters. Other models of loop catheters have not been tested with the Vdrive™ system.

The Vdrive™ with V-Sono™ disposable is indicated for remotely controlling the advancement, retraction, rotation and anterior-posterior deflection of compatible ultrasound catheters inserted into the right atrium. Compatible catheters at this time include Biosense Webster, Inc. Soundstar™ 3D Ultrasound Catheters and Acuson AcuNav™ Ultrasound Catheters. Other models of ICE catheters have not been tested with the Vdrive™ system.

The Vdrive Duo™ is an optional accessory intended for remotely controlling the Vdrive™ system when one arm of the device is equipped with a V-Loop™ disposable set and the other arm is equipped with the V-Sono™ disposable set. During the procedure, the Vdrive Duo™ allows selection between the disposable sets (V-Loop™ or V-Sono™).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary per 21CFR §807.92

Submitter's information

Stereotaxis, Inc.
4320 Forest Park Ave, Suite 100
St. Louis, MO 63108
Contact: John Nadelin, VP Regulatory & Quality
Telephone: 314-678-6130

Device/ classification name

Device Name:	Vdrive™, Vdrive Duo™
Classification/Common name:	System, Catheter Control, Steerable
Classification Number:	870.1290
Product Code:	DXX, DQX
Classification Panel:	Cardiovascular
Currently Marketed Substantially Equivalent Device:	Vdrive™ with V-Sono™ (K122659)

Device description

The Vdrive™ with V-Loop™ is provides a remote method of controlling the advancement, retraction, rotation, tip deflection, and loop size of a LASSO® Circular Mapping catheter during electrophysiology procedures and is comprised of four major components:

1. Vdrive™ Hardware - control box, adjustable arm, drive unit and support structure or Vdrive Duo™ (K133396), with two adjustable arms,
2. Vdrive™ User Interface – combination of software-driven 1) Tableside Controller and 2) dedicated Vdrive™ Controller,
3. V-Loop™ Disposable Kit – Handle Clamps (w/catheter inserts), Telescoping Catheter Support and Drape. These components are disposable, sterile, single use devices, and
4. V-Sono™ Disposable Kit (K122659) if Vdrive Duo™ will be used.

Intended use

The Vdrive™ system is intended to stabilize, navigate and remotely control:

- compatible loop (circular) mapping catheters to facilitate movement of the catheter during the performance of electrophysiological procedures when used in conjunction with the V-Loop™ disposable sets in the Vdrive™ system.
- compatible Intracardiac Echocardiography (ICE) catheters to facilitate visualization of cardiac structure during the performance of cardiac procedure when used in conjunction with the V-Sono™ disposable sets in the Vdrive™ system.

The Vdrive™ with V-Loop™ disposable is indicated to remotely control the advancement, retraction, rotation, tip deflection and loop size of compatible loop catheters inserted across the septum into the left atrium using conventional procedures. Compatible catheters at this time include Biosense Webster Lasso 2515 and Lasso 2515 NAV Circular Mapping Catheters. Other models of loop catheters have not been tested with the Vdrive™ system.

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The Vdrive™ with V-Sono™ disposable is indicated for remotely controlling the advancement, retraction, rotation and anterior-posterior deflection of compatible ultrasound catheters inserted into the right atrium. Compatible catheters at this time include Biosense Webster, Inc. Soundstar™ 3D Ultrasound Catheters and Acuson AcuNav™ Ultrasound Catheters. Other models of ICE catheters have not been tested with the Vdrive™ system.

The Vdrive Duo™ is an optional accessory intended for remotely controlling the Vdrive™ system when one arm of the device is equipped with a V-Loop™ disposable set and the other arm is equipped with the V-Sono™ disposable set. During the procedure, the Vdrive Duo™ allows selection between the disposable sets (V-Loop™ or V-Sono™).

Technological characteristics

Device Characteristic	Proposed Vdrive™ with V-Loop™, Vdrive Duo™	Currently Marketed Vdrive™ with V-Sono™
Location of Catheter tip	Right side of heart	Right or left side of heart
Initial Placement of catheter	Manual placement by cardiac electrophysiologist	Manual placement by cardiac electrophysiologist
Catheter Movement	Mechanical	Mechanical
Variable Speed	Yes	Yes
Catheter Movement	Continuous	Continuous
Emergency Stop Option	Manual	Manual
Manual Override	Yes	Yes
Single Use	Disposable is single use	Disposable is single use
Sterilization Method	EtO	EtO
Control of catheter movement	Mechanical	Mechanical
Compatible Catheters	LASSO® 2515 Variable Circular Mapping Catheter, LASSO® 2515 NAV LASSO ® 2515 ECO NAV Variable Circular Mapping Catheter (Biosense Webster)	Soundstar™ 3D Ultrasound Catheters (Biosense Webster) AcuNav™ Ultrasound Catheters (AcuNav)
Catheter movements	Advancement-retraction Rotation Tip deflection Loop size	Advancement-retraction Rotation Anterior-posterior deflection

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Device Characteristic	Proposed Vdrive™ with V-Loop™, Vdrive Duo™	Currently Marketed Vdrive™ with V-Sono™
Control Room User Interface	Yes	Yes
SW driven	Yes	Yes
Simultaneous Use of two Vdrive™ Disposables	Yes	No

Performance data

Performance data established the substantial equivalence of the Vdrive™ with V-Loop™ compared to the predicate device. Performance data included software verification and validation data, bench performance testing to verify that specifications were met, animal testing, and a prospective randomized multi-center clinical trial of the Vdrive™ with V-Loop™ system in navigation of circular mapping catheters compared to conventional manual methods of navigation. Performance testing was conducted for electrical safety, EMC compatibility, sterilization and shelf life and packaging.

Animal Testing: Stereotaxis performed an animal study in a porcine model to evaluate the safety and effectiveness of the Vdrive™ with V-Loop™ to perform navigation, electrogram generation, mapping and pacing during navigation, product usability and extremes of use. This study demonstrated that Vdrive™ with V-Loop™ met its performance and user requirements.

Clinical Testing: Stereotaxis performed a prospective, randomized multi-center clinical trial of the Vdrive™ with V-Loop™ system in navigation of circular mapping (loop) catheters compared to conventional manual methods of navigation. A total of 137 subjects were randomized 2:1 (Vdrive™: Control) at five (5) clinical sites. Actual enrollment was 77 Vdrive™ and 43 control group subjects who were scheduled to undergo elective electrophysiology (EP) studies and a planned ablation procedure for pulmonary vein (PV) isolation, and who required the use of a circular mapping catheter to evaluate the PVs. Results of the efficacy analysis demonstrated that the Stereotaxis Vdrive™ with V-Loop™ is effective when used to control a circular mapping system catheter when compared to manual navigation; the Vdrive™ with V-Loop™ is non-inferior to the manual procedure. The safety analysis led to the conclusion that similar adverse events between groups, and that the low rate of adverse events was unrelated to use of the Vdrive™ system. Vdrive Duo™ was used to control two different disposables in a total of 33 subjects in the VERSATILE trial.

Based upon the documentation presented in this 510(k) it has been demonstrated that the Vdrive™ with V-Loop™ device is safe and effective for its intended use.

Date summary prepared: September 3, 2014